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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,908	11/26/2003	Peter Andersen	0459-0752P	5514
2252	7590	12/31/2009		
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
			EXAMINER	
			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
NOTIFICATION DATE	DELIVERY MODE			
12/31/2009	ELECTRONIC			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/723,908	<b>Applicant(s)</b> ANDERSEN ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 November 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11,14-18,27 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 2 and 3 is/are allowed.
- 6) Claim(s) 1,4-11,14-18,27 and 46-50 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

##### **1. THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**

2. Applicants' Response to Office Action, received 19 November 2009, is acknowledged.

Claims 4 and 17 have been amended. Claim 12 has been cancelled.

3. Claims 1-11, 14-18, 27 and 46-50.

#### **Objection Moot**

4. The objection to claim 12 under 37 CFR 1.75 as being a substantial duplicate of claim 1 is moot in light of the cancellation of the claims.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4-11, 14-18, 27 and 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a substantially pure polypeptide selected from the group consisting of a short peptide of  $\geq 7$  consecutive amino acids and  $\leq 10$  consecutive amino acids, an oligopeptide of  $\geq 11$  consecutive amino acids and  $\leq 100$  consecutive amino acids and a longer polypeptide of  $\geq 101$  consecutive amino acids and  $\leq 150$  consecutive amino acids, wherein said substantially pure polypeptide comprises (a) an amino acid sequence encoded by a member of the *esat-6* gene family, (b) or comprises an amino acid analogue having a sequence identity with a polypeptide encoded by a member of the *esat-6* gene family of  $\geq 94\%$ , wherein (b) is immunologically equivalent to the polypeptide encoded by a member of the *esat-6* gene family, with the proviso that the substantially pure polypeptide is not selected from the group

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consisting of Rv0287, Rv0288, Rv1037c, Rv1038c, Rv1197, Rv1198, Rv1792, Rv1793, Rv2346c, Rv2347c, Rv3019c, Rv3619c, Rv3620c, Rv3874, and Rv3875.

Page 3, lines 30-33, Table 1 and Table 3 of the specification list the polypeptides encoded by a member of the *esat-6* gene family. Excluding the peptides in the proviso, the group from which a polypeptide can be selected consists of Rv1036c (SEQ ID NO:7), Rv2348c (SEQ ID NO:13), Rv2653c (SEQ ID NO:15), Rv2654c (SEQ ID NO:17), Rv3020c (SEQ ID NO:19), Rv3444c (SEQ ID NO:21), Rv3445c (SEQ ID NO:23), Rv3890c (SEQ ID NO:25), Rv3891c (SEQ ID NO:27), Rv3904c (SEQ ID NO:29) and Rv3905c (SEQ ID NO:31).

However, a review of the specification has unveiled a discrepancy for Rv1036c. The length of the peptide Rv1036c differs in Table 1 (100 amino acids), Table 3 (112 amino acids) and the sequence listing (112 amino acids). Thus, it is unclear from the teachings in the specification which sequence should be utilized in order to determine which polypeptides can be included or excluded from the scope of claim 1.

Claims 4-11, 14-18, 27 and 46-50 depend from claim 1, but do not clarify the issue.

### **Conclusion**

6. Claims 1, 4-11, 14-18, 27 and 46-50 are rejected.
7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 29, 2009